

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

LYNN WHITE and NATALIYA )  
BIRMAN, individually and on )  
behalf of all others similarly situated, )

Plaintiff, )

v. )

GLAXOSMITHKLINE PLC, )  
GLAXOSMITHKLINE )  
LLC, SANOFI S.A., SANOFI-AVENTIS )  
U.S. LLC, SANOFI US SERVICES INC., )  
AND CHATTEM, INC., GLENMARK )  
PHARMACEUTICALS LTD., )  
GLENMARK GENERICS LTD., )  
GLENMARK GERNICS, INC., USA, )  
DR. REDDY'S LABORATORIES, )  
SA, and DR. REDDY'S LABORATORIES, )  
INC., )

Defendants. )

No.

JURY TRIAL DEMANDED

**CLASS ACTION COMPLAINT**

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Plaintiff Lynn White and Nataliya Birman, on behalf of themselves and all others similarly situated, by and through counsel and pursuant to the Federal Rules of Civil Procedure, brings this Class Action Complaint against Defendants GlaxoSmithKline plc, GlaxoSmithKline, LLC, Sanofi S.A., Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., Chattem, Inc., Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd., Glenmark Generics, Inc. USA, Dr. Reddy's Laboratories, SA, and Dr. Reddy's Laboratories, Inc. ("Defendants"), and allege the following based on personal knowledge, the investigation of counsel, and information and belief:

### **INTRODUCTION**

1. Zantac has been a darling of the pharmaceutical industry since it was first approved by the Food and Drug Administration ("FDA") for prescription use in 1983. Zantac is the brand name of a drug called ranitidine, which is used to treat gastrointestinal disorders, such as acid indigestion, heartburn, GERD, and sour stomach, by decreasing the amount of acid produced by the stomach.

2. By 1988, Zantac became one of the world's best selling drugs, and one of the first drugs ever to surpass \$1 billion in sales. Through 2018, Zantac remained of the world's most popular and financially successful drugs, and global sales of nonprescription Zantac reportedly totaled approximately \$142 million. Zantac's dominance and staying-power has been attributed to the aggressive and inventive marketing strategy of its developer, GlaxoSmithKline plc, and to the belief by its users, such as Plaintiffs Lynn White and Nataliya Birman, that ranitidine, including Zantac, was completely safe.

3. But, as it turns out, ranitidine is not safe. It produces high quantities of N-nitrosodimethylamine (NDMA) in the body, a chemical that according to the World Health

Organization is “clearly carcinogenic.”<sup>1</sup> On September 13, 2019, the FDA issued a statement announcing the presence of NDMA in ranitidine, including Zantac. The FDA and some of the Defendants have referred to the presence of NDMA in Zantac as an “impurity,” suggesting a contamination in the manufacturing process, but this is wildly inaccurate. Instead, NDMA is created when ranitidine, including Zantac, is taken for its intended use; that is, when it is ingested and combined with stomach acids and contents.

4. Several manufacturers of Zantac, including its developer, GlaxoSmithKline plc, and Sanofi-Aventis U.S. LLC, which distributes over-the-counter Zantac in the United States, have recently issued recalls and halted sales, and certain pharmacies and stores have pulled Zantac from their shelves. Yet GlaxoSmithKline plc and Sanofi-Aventis U.S. LLC continue to stand behind the safety of the of Zantac, despite evidence that Zantac has been linked to NDMA.

5. Since 1987, or for over 32½ years, Lynn White has taken 150 mg of Zantac at least once, but oftentimes twice, a day to reduce the acid in her stomach and alleviate related complications, trusting and believing that it was safe. She has spent well over \$14,000 purchasing Zantac during this time period. She has recently learned about Zantac’s dangerous properties and stopped taking it, but now lives in constant fear of developing cancer.

6. Through most of 2019, Nataliya Birman has taken 150 mg of generic ranitidine once a day to alleviate stomach pain and upset, trusting and believing that it was safe. After learning about ranitidine’s dangerous properties and having stopped taking the drug, she now lives in constant fear of developing cancer.

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<sup>1</sup> R.G. Liteplo, et al., *Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine*, WORLD HEALTH ORGANIZATION (2002), available at <https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf> (last visited 11/12/19).

## **THE PARTIES**

### **A. Plaintiffs**

#### **1. Lynn White**

7. Plaintiff Lynn White is and was a citizen of the State of New Jersey and the United States at all times relevant to this action.

8. From April of 1987 through November of 2019, Ms. White took Zantac at least once a day, but often two times a day, to help reduce the acid in her stomach that caused acid reflux and sour mouth. She was first prescribed Zantac 150 mg two times a day by her physician in 1987. She purchased and took prescription Zantac from 1987 through the end of 2016 or early 2017, at which time she began taking an over-the-counter Zantac at the same dosage, 150 mg once or twice daily.

9. For over 32 years, Ms. White purchased and took prescription Zantac manufactured and sold by the GlaxoSmithKline Defendants, and then at the end of 2016 or early 2017, over-the-counter Zantac manufactured and sold by the Sanofi Defendants.

10. Around September of 2019, contrary to what she had believed these past 32 years, Ms. White learned for the first time that Zantac was not safe because it contains “impurities” linked with a cancer-causing agent and has the potential to cause cancer.

11. Because she believed and relied on Defendants’ representations and purchased Zantac all the while trusting that it was safe, Ms. White is now at an increased risk for developing various types of cancer, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

12. Ms. White never would have purchased and taken Zantac had she known that the Defendants misrepresented its true nature, she has been taking a “cancer pill” for decades, that it

would subject her to a significantly increased risk of developing various types of cancer, and that she would be subjected to a constant and nagging fear and dread that she will develop cancer.

**2. Nataliya Birman**

13. Plaintiff Nataliya Birman is and was a citizen of the State of Illinois and the United States at all times relevant to this action.

14. From January of 2019 until April of 2019, she purchased and took over-the-counter Zantac that she purchased at Target which was manufactured by the Dr. Reddy's Defendants. In April of 2019, Ms. Birman's doctor prescribed ranitidine, and from April of 2019 until July of 2019, Ms. Birman purchased and used prescription ranitidine manufactured and sold by the Glenmark Defendants, believing it to be safe. Then in August of 2019 until September of 2019, she continued to use over-the-counter generic ranitidine manufactured by the Dr. Reddy's Defendants.

15. In September of 2019, she learned about ranitidine's dangerous properties, and that it has been linked with a cancer-causing agent and has the potential to cause cancer

16. Because she believed and relied on Defendants' representations and purchased ranitidine all the while trusting that it was safe, Ms. Birman is now at an increased risk for developing various types of cancer, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

17. Ms. Birman never would have purchased and taken ranitidine had she known that the Defendants misrepresented its true nature, that she has been taking a "cancer pill" this year, that it would subject her to a significantly increased risk of developing various types of cancer, and that she would be subjected to a constant and nagging fear and dread that she will develop cancer.

## **B. Defendants**

### **1. The GSK Defendants**

18. Defendant GlaxoSmithKline plc, is an English corporation with its global headquarters and principal place of business at 980 Great West Road, Brentford, Middlesex, England. Defendant GlaxoSmithKline plc is the successor-in-interest to the companies that initially developed, patented, and commercialized the molecule known as ranitidine in the 1970s. In 1983, Glaxo Holdings, Ltd., now part of GlaxoSmithKline PLC, was awarded approval by the FDA to sell Zantac in the United States.

19. Defendant GlaxoSmithKline LLC is a Delaware limited liability corporation with its principal place of business at 5 Crescent Drive, Philadelphia, Pennsylvania, 19112. Since 1983, GlaxoSmithKline LLC, either directly, or through a subsidiary, has marketed and sold prescription Zantac in the United States (collectively “GSK” or “GSK Defendants”).

### **2. The Sanofi Defendants**

20. Defendant Sanofi S.A. is French corporation with its headquarters and principal place of business at 54, Rue La Boétie, Paris.

21. Defendant Sanofi U.S. LLC, f/k/a Sanofi-Aventis U.S. LLC, is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey, 08807. Sanofi U.S. LLC is a wholly owned subsidiary of Sanofi S.A.

22. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey, 08807. Sanofi U.S. Services Inc. is a wholly owned subsidiary of Sanofi S.A.

23. Defendant Chattem, Inc., is a Tennessee corporation with a principal place of business at 1715 West 38<sup>th</sup> Street, Chattanooga, Tennessee, 37409. Chattem, Inc. is a wholly owned subsidiary of Sanofi S.A.



24. Defendants Sanofi S.A., Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively “Sanofi” or “Sanofi Defendants”) controlled the rights in the United States to manufacture and distribute over-the-counter Zantac from about January 2017 to the present.

### **3. The Glenmark Defendants**

25. Glenmark Pharmaceuticals Ltd. is an Indian corporation with its headquarters and a principal place of business at Glenmark House, HDO-Corporate building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India.

26. Glenmark Generics Ltd. is an Indian corporation with its headquarters and a principal place of business at Glenmark House, HDO-Corporate building, Wing -A, B D Sawant Marg, Chakala, Off Western Express Highway, Mumbai 400099, Maharashtra, India. Glenmark Generics Ltd. is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd.

27. Glenmark Generics, Inc. USA is a Delaware corporation with a principal place of business at 750 Corporate Drive, Mahaw, New Jersey 07430. Glenmark Generics, Inc. USA is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd and the North American Division of Glenmark Generics Ltd.

28. Defendants Glenmark Pharmaceuticals Ltd., Glenmark Generics Ltd., and Glenmark Generics, Inc. USA (collectively “Glenmark” or “Glenmark Defendants”) manufactured and sold prescription ranitidine in the United States after November, 2008.

### **4. The Dr. Reddy’s Defendants**

29. Dr. Reddy’s Laboratories SA is an Indian corporation with its and headquarters and a principal place of business at 7-1, 27, Ameerpet Rd. Leelangar, Ameerpet, Hyderabad, Telangana 500016, India.

30. Dr. Reddy's Laboratories, Inc. is a New Jersey corporation with its principal place of business at 107 College Rd. E, Princeton, New Jersey 08540. Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, SA.

31. Dr. Reddy's Laboratories SA and Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's Defendants") manufactured and sold ranitidine in the United States in stores such as Target.

### **JURISDICTION AND VENUE**

32. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, as amended by the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2), because (a) there are at least 100 class members; (b) the matter in controversy exceeds \$5 million, exclusive of interest and costs; (c) at least one Plaintiff and is a citizen of a different state than at least one Defendant; and (d) members of the class, including Plaintiff, are citizens of a state and at least one of the Defendants is a citizen or subject of a foreign state.

33. The Court has personal jurisdiction over the Defendants because they have sufficient minimum contacts in Illinois to render the exercise of jurisdiction by this Court proper and fair.

34. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) and (c)(2) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

### **FACTUAL ALLEGATIONS**

#### **A. A Relevant History of Zantac**

35. In 1983, Glaxo Holdings Ltd., now part of GlaxoSmithKline PLC, received FDA approval for Zantac. Zantac is the brand name of a drug called ranitidine, which is used to treat gastrointestinal disorders, such as acid indigestion, heartburn, GERD, and sour stomach, by

decreasing the amount of acid produced by the stomach.<sup>2</sup> Ranitidine is a histamine type 2-receptor antagonist.<sup>3</sup> When it launched Zantac, GSK embarked on an aggressive and novel marketing strategy<sup>4</sup> which only five years later, made Zantac one of the world's best selling drugs and one of the first drugs to top \$1 billion on sales.

36. Since its launch in 1983, the GSK Defendants sold prescription Zantac in the United States.

37. In 1996, Zantac was first approved by the FDA for over-the-counter sales, and it was sold by Warner-Lambert (during part of that time in a joint venture with GSK), until Warner-Lambert was acquired by Pfizer, Inc. in June 2000.

38. Then in 1997, GSK's United States patent for ranitidine expired and generic version of ranitidine became available through other manufacturers. One of those manufacturers who entered the market to sell prescription ranitidine in the United States was Glenmark Generics, Inc. USA. In or around November, 2008, Glenmark Generics, Inc. USA received FDA approval to manufacture, market and sell generic ranitidine.<sup>5</sup>

39. As for over-the-counter brand name Zantac, from mid-2000 until 2006, Pfizer marketed and sold it until Boehringer Ingelheim Pharmaceuticals, Inc. acquired the rights to it in

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<sup>2</sup> The Prescriber's Digital Reference, found at <https://www.pdr.net/drug-summary/Zantac-150-and-300-Tablets-ranitidine-hydrochloride-241.3325> (last visited 11/12/19). *See also* <https://www.zantacotc.com/zantac-maximum-strength.html#learn-more> (last visited 11/18/19).

<sup>3</sup> The Prescriber's Digital Reference, *supra*.

<sup>4</sup> Wright, R, How Zantac Became the Best-Selling Drug in History, 16(4) J. HEALTHCARE MARKETING 24 (Winter 1996), Abstract found at <https://www.ncbi.nlm.nih.gov/pubmed/10169076> (last visited 11/12/19).

<sup>5</sup> Ghangurde, Anju, "Glenmark receives FDA ok for ranitidine," (Nov. 24, 2009), found at <https://medtech.pharmaintelligence.informa.com/SC032085/Glenmark-receives-FDA-ok-for-ranitidine> (last visited 11/21/19).

late 2006. Boehringer manufactured and sold over-the-counter Zantac in the United States from that time until January, 2017, when the Sanofi Defendants acquired the rights to it.

40. Since January, 2017, the Sanofi Defendants have manufactured and sold over-the-counter Zantac in the United States.

41. Through 2018, Zantac was one of the world's most popular and financially successful drugs, and global sales of nonprescription Zantac reportedly totaled approximately \$142 million, up almost 14% year over year.<sup>6</sup> Many have attributed its success to the widely-held perception of its safety.<sup>7</sup>

42. In fact, ranitidine is listed on the World Health Organization's List of Essential Medicines, which are a selection of drugs the organization has determined are "the most efficacious, safe and cost-effective medicines for priority conditions."<sup>8</sup>

**B. Scientific Research from as Early as 1990 Documented Ranitidine's Dangerous Properties**

43. During the time Defendants were respectively manufacturing, marketing, and selling ranitidine, including Zantac, Defendants knew or should have known about ranitidine's dangerous properties based on published, scientific research.

44. Ms. White and Ms. Birman, being laypersons, had no knowledge of or access to this scientific literature or information.

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<sup>6</sup> "Over-the-counter Zantac recalled in U.S. and Canada," (Oct. 18, 2019), found at <https://www.supermarketnews.com/health-wellness/over-counter-zantac-recalled-us-and-canada> (last visited 11/13/19).

<sup>7</sup> Valisure Citizen Petition on Ranitidine ("Citizen Petition") (Sept. 9, 2019), p.1, found at <https://www.valisure.com/about-us/> (last visited 11/14/19).

<sup>8</sup> World Health Organization Model List of Essential Medicines, 21<sup>st</sup> List (2019), <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf> (last visited 11/18/19).

45. At no time during Defendants' respective manufacturing, marketing, and selling of prescription and over-the-counter ranitidine, including Zantac, did any Defendant include a warning about NDMA or cancer to the label and/or packaging.

46. As early as 1990, Japanese researchers found that NDMA concentrations in gastric juice doubled in gastric ulcer patients taking ranitidine compared to those who were not taking it.<sup>9</sup>

47. Defendants manufacturing and selling ranitidine at that time and thereafter knew or should have known of the connection between ranitidine, gastric juices and increases in NDMA concentrations, or, at a minimum, should have themselves investigated and researched the connection.

48. A 2004 study discovered a connection between Zantac and bladder cancer. The study examined men with self-reported peptic ulcers and found that those who were taking either Zantac (ranitidine) or Tagamet (cimetidine) had a heightened risk of bladder cancer.<sup>10</sup> "Recent use of ulcer treatment medication (Tagamet and Zantac) was [ ] related to the risk of bladder cancer...."<sup>11</sup>

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<sup>9</sup> Matsuda, J., Hinuma, K., Tanida, N., Tamura, K., Ohno, T., Kano, M. & Shimoyama, T., "N-nitrosamines in gastric juice of patients with gastric ulcer before and during treatment with histamine H2-receptor antagonists," GASTROENTEROL JAPAN, (April 25, 1990), abstract found at <https://www.ncbi.nlm.nih.gov/pubmed/1971799> (last visited 11/13/19); see also Zeng, Teng & Mitch, William A., "Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine," CARCINOGENESIS, Vol 37, Issue 6 (June 2016), found at <https://academic.oup.com/carcin/article/37/6/625/1744630> (summarizing the results of the Matsuda Study at 626 & n.16 (last visited 11/13/19).

<sup>10</sup> Michaud, Dominique S., Mysliwiec, Pauline A., Aldoori, Walid, Willett, Walter C., & Giovannucci, Edward, "Peptic Ulcer Disease and the Risk of Bladder Cancer in a Prospective Study of Male Health Professionals," CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION (Feb. 2004), found at <https://cebp.aacrjournals.org/content/13/2/250.long#ref-9> (last visited 11/13/18).

<sup>11</sup> *Id.*

49. Although the study did not distinguish between the two medications, Defendants manufacturing and selling Zantac at the time this study was published and thereafter knew or should have known of its potentially cancer-causing properties or, at least, should have themselves investigated and researched the issue.

50. A 2016 Stanford University study found that oral intake of Zantac resulted in NDMA in urine.<sup>12</sup> The study gave 10 healthy volunteers 150 milligrams of Zantac and found that subsequent NDMA levels in their urine exceeded 47,000 nanograms (ng). The FDA's permissible daily intake limit of NDMA is 96 ng. The study found that the urinary excretion of NDMA was "far higher than estimated daily dietary intakes," but noted that because most of the NDMA would have been metabolized before reaching the urine, "[a]ctual systemic NDMA exposure [in the body] is likely much higher than that eliminated in the urine."<sup>13</sup> It concluded "that ranitidine either served as a direct precursor for the [internal] formation of NDMA or produced NDMA precursors [in the body]."<sup>14</sup>

51. The Stanford study recommended further research: "due to the widespread use of ranitidine, the increase in urinary NDMA excretion suggests the need for a more comprehensive risk assessment relevant to chronic ranitidine use...."<sup>15</sup> It highlighted a void in scientific research never before conducted regarding Zantac: "To the best of our knowledge, no previous study has demonstrated conversion of ranitidine to NDMA at stomach-relevant pH. Only scant, and inconclusive data exists for the impact of ranitidine intake on N-nitrosamine levels in human

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<sup>12</sup> Zeng, Teng & Mitch, William A., "Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine," *CARCINOGENESIS*, Vol 37, Issue 6 (June 2016), found at <https://academic.oup.com/carcin/article/37/6/625/1744630> (last visited 11/13/19).

<sup>13</sup> *Id.* at 632 (emphasis added).

<sup>14</sup> *Id.* at 631.

<sup>15</sup> *Id.*

gastric juice.”<sup>16</sup> N-nitrosamines are considered “likely human carcinogens” and have been implicated as inducing stomach, esophagus, and nasopharynx cancers, and as agents for bladder cancer.<sup>17</sup>

52. While Zantac’s original manufacturer GSK, published a study of ranitidine’s metabolites in urine in 1981,<sup>18</sup> that study did not look for NDMA.<sup>19</sup>

53. Defendants manufacturing and selling Zantac at the time the Stanford study was published and thereafter knew or should have known about the excretion of NDMA after taking ranitidine or, at least, should have themselves investigated and researched the issue as the study suggested.

### **C. Valisure’s 2019 Testing and Citizen Petition**

54. Valisure is an on-line pharmacy which also operates an accredited laboratory which tests each pharmaceutical or supplement it sells. Its mission is to bring transparency and increased quality to the pharmaceutical industry.<sup>20</sup>

55. In June of 2019, Valisure first alerted the FDA “of the link of Zantac and its generics to the carcinogen NDMA” during routine testing.<sup>21</sup>

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<sup>16</sup> *Id.* at 625-26 (footnotes omitted).

<sup>17</sup> *Id.* at 625.

<sup>18</sup> See Carey, P.F., Martin, L.E. & Owen, P.E, “Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography, JOURNAL OF CHROMATOGRAPHY B: BIOMEDICAL SCIENCES AND APPLICATIONS, Vol. 225, Issue 1 (Sept 11, 1981), *cited by* Lewis, Tanya, “What we Know about the Possible Carcinogen Found in Zantac,” *Scientific American* (10/28/19), found at <https://www.scientificamerican.com/article/what-we-know-about-the-possible-carcinogen-found-in-zantac/> (last visited 11/13/19).

<sup>19</sup> See Lewis, Tanya, “What we Know about the Possible Carcinogen Found in Zantac,” *Scientific American*, *supra*.

<sup>20</sup> See <https://www.valisure.com/about-us/> (last visited 11/14/19).

<sup>21</sup> “Valisure detects NDMA in ranitidine, found at <https://www.valisure.com/blog/uncategorized/detection-of-ndma-in-raniditine/> (last visited 11/14/19).

56. On September 9, 2019, Valisure filed a Citizen Petition on Ranitidine with the FDA, asking the FDA to “recall and suspend sales of ranitidine from the US market” because it “has detected NDMA in excess of 3,000,000 ng per tablet when analyzing ranitidine products, likely due to an inherent instability of the ranitidine molecule.”<sup>22</sup>

57. In the medication that Plaintiff Lynn White has taken since 1987, Valisure found 2,511,469 ng of NDMA,<sup>23</sup> which is over 26,000 times the FDA’s permissible daily intake of 96 ng:

**Table 1. Ranitidine samples tested for NDMA.**

All ranitidine samples tested by Valisure’s laboratory formed very high levels of NDMA.

Attachment B contains detailed data from each test.

150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)	Attachment B Data Reference #
Reference Powder*	125619	2,472,531	1
Zantac, Brand OTC	18M498M	2,511,469	2
Zantac (mint), Brand OTC	18H546	2,834,798	3
Wal-Zan, Walgreens	79L800819A	2,444,046	4
Wal-Zan (mint), Walgreens	8ME2640	2,635,006	5
Ranitidine, CVS	9BE2773	2,520,311	6
Zantac (mint), CVS	9AE2864	3,267,968	7
Ranitidine, Equate	9BE2772	2,479,872	8
Ranitidine (mint), Equate	8ME2642	2,805,259	9
Ranitidine, Strides	77024060A	2,951,649	10

\* Estimated NDMA scaled to equivalent of 150 mg.

58. Valisure also conducted testing under conditions that more closely resembled the human stomach, and nevertheless found high levels of NDMA when combined with nitrates commonly found in certain foods and produced by stomach bacteria:<sup>24</sup>

<sup>22</sup> Valisure Citizen Petition on Ranitidine (“Citizen Petition”) (Sept. 9, 2019), p.1, found at <https://www.valisure.com/about-us/> (last visited 11/14/19).

<sup>23</sup> *Id.* at 6, Table 1.

<sup>24</sup> *Id.* at 7, Table 2.



**Table 2. Biologically relevant tests for NDMA formation.**

Conditions tested in Valisure's laboratory produced high levels of NDMA from ranitidine. NDMA was detected in conditions of simulated gastric fluid with sodium nitrite, which is found in certain foods and produced by bacteria in the stomach.

<b>Ranitidine Tablet Studies Lot# 77024060A</b>	<b>NDMA (ng/mL)</b>	<b>NDMA per tablet (ng)</b>	<b>Attachment B Data Reference #</b>
Tablet without Solvent	Not Detected	Not Detected	11
Tablet	Not Detected	Not Detected	12
Simulated Gastric Fluid ("SGF")	Not Detected	Not Detected	13
Simulated Intestinal Fluid	Not Detected	Not Detected	14
SGF with 10 mM Sodium Nitrite	Not Detected	Not Detected	15
SGF with 25 mM Sodium Nitrite	236	23,600	16
SGF with 50 mM Sodium Nitrite	3,045	304,500	17

59. Valisure suggested that the ranitidine molecule is unstable such that NDMA "likely comes from no other source than the ranitidine molecule itself."<sup>25</sup> Valisure concluded, "Combined with other data from Valisure and the scientific works of Stanford University and others, the evidence presented shows this instability and the resulting NDMA occurs in the conditions representative of those in the human body and builds a compelling case for ranitidine being a likely human carcinogen."<sup>26</sup>

60. Valisure examined several historical research studies<sup>27</sup> stating, "NDMA formation in the stomach **has been a concern for many years** and specifically ranitidine has been implicated as a cause of NDMA formation by multiple research groups including those at Stanford University."<sup>28</sup>

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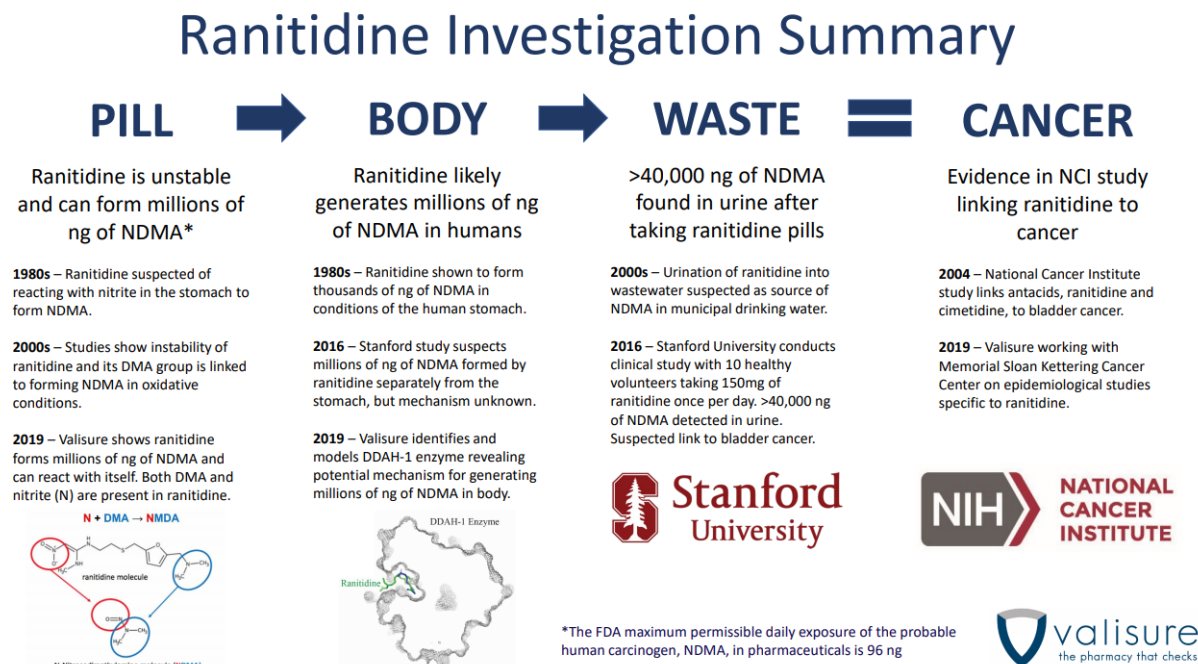
<sup>25</sup> *Id.* at 5.

<sup>26</sup> *Id.* at 2.

<sup>27</sup> *Id.* at 10-12.

<sup>28</sup> *Id.* at 8 (emphasis added).

61. Valisure graphically summarized its opinions, and those historical findings of certain studies:<sup>29</sup>



62. Valisure also examined the studies that supported the FDA’s approval process for the drug and found “these studies [ ] insufficient to rule out potentially carcinogenic properties and, in fact, reveal weaknesses in testing methodology that likely enabled this specific issue to avoid detection” for the past 38 years.<sup>30</sup>

### D. The FDA Statements

63. On September 13, 2019, a week after Valisure submitted its Citizen Petition to the FDA, the FDA issued a statement announcing the presence of NDMA in ranitidine.<sup>31</sup> The FDA’s

<sup>29</sup> *Id.*, Attachment D.

<sup>30</sup> *Id.* at 4, 13.

<sup>31</sup> “9/13/19: Statement – Statement alerting patients and health care professionals of NDMA found in samples of ranitidine,” found at <https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine> (last visited 11/12/19).

statement is contradictory, at best, and misleading, at worst. It explained that “some” ranitidine medicines, including Zantac, contain an “impurity” called NDMA at “low levels.” It asserted that NDMA “is found in water and foods, including meats, dairy products, and vegetables,” and reported to be testing whether those “low levels of NDMA in ranitidine pose a risk to patients.” Although the FDA admitted that “NDMA may cause harm in large amounts,” it is stated that findings from preliminary tests show that NDMA “barely exceed amounts you might expect to find in common foods.”

64. On October 2, 2019, the FDA issued an update, reporting that it was “continuing to test ranitidine products from multiple manufacturers and [ ] assessing the potential impact on patients who have been taking ranitidine.”<sup>32</sup> The FDA launched into a detailed and scientific explanation of testing protocols used by the FDA versus “a third-party laboratory,” undoubtedly referring to Valisure, which showed differing results when tests were performed at higher versus lower temperatures.<sup>33</sup>

65. Despite what appears to be the FDA’s criticism of Valisure’s testing, buried at the bottom of the FDA’s update is a sentence which showed that the FDA changed its opinion: “the agency’s early, limited testing has found **unacceptable levels of NDMA in samples of ranitidine.**”<sup>34</sup>

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<sup>32</sup> “10/2/19: Update - FDA provides an update on testing for ranitidine for NDMA impurities,” found at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine> (last visited 11/13/19).

<sup>33</sup> Notably, Valisure’s Citizen Petition made clear that it developed a test that detected NDMA even when samples were only heated to 37 degrees Celsius, the temperature of the human body, in simulated gastric fluid with varying amounts of nitrites typically found in foods such as processed meats. Valisure nevertheless found a “highly efficient conversion of ranitidine to NDMA.” Citizen Petition at 3. The FDA seemingly ignored that Valisure performed low temperature testing.

<sup>34</sup> FDA 10/2/19 Update, *supra*, (emphasis added).

**E. Voluntary Product Recalls by Certain Defendants Yet Assurances About Zantac's Safety**

66. After Valisure filed its Citizen Petition, and in the wake of conflicting statements from the FDA, various manufacturers voluntarily recalled their respective Zantac and ranitidine products.<sup>35</sup>

67. Around September 26, 2019, Walgreens stopped selling ranitidine products, including the prescription generic ranitidine manufactured and sold by the Glenmark Defendants.<sup>36</sup>

68. On October 6, 2019, GSK announced that it was recalling prescription Zantac as a precaution.<sup>37</sup>

69. On October 18, 2019, Sanofi recalled over-the-counter Zantac in the United States and Canada.<sup>38</sup>

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<sup>35</sup> See “9/24/19: Press release – FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity;” “9/26/19: Statement – FDA alerts health care professions and patients to voluntary recall of ranitidine medicines,” (Walgreens, Walmart, Rite-Aid, and Apotex Corp.); “10/28/19: Update – FDA alerts health care professionals and patients to multiple voluntary recalls of ranitidine,” (Perrigo Co., Novitium Pharma LLC, Lannett Co., Inc.); “11/8/19: Update – FDA alerts patients and health care professionals to Aurobindo’s recall of prescription and over-the-counter ranitidine;” “11/12/19: Update – FDA alerts patients and health care professions to voluntary recalls of ranitidine,” (Amneal, American Health Packaging); all found at <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine> (last visited 11/13/19).

<sup>36</sup> “9/24/19: Press release – FDA announces voluntary recall of Sandoz ranitidine capsules following detection of an impurity;” “9/26/19: Statement – FDA alerts health care professions and patients to voluntary recall of ranitidine medicines,” *supra*.

<sup>37</sup> <https://www.fiercepharma.com/manufacturing/gsk-joins-other-drugmakers-recalling-zantac-products> (last visited 11/14/19).

<sup>38</sup> “Sanofi to conduct precautionary voluntary recall of Zantac OTC in U.S. and Canada,” found at <http://www.news.sanofi.us/2019-10-18-Sanofi-to-conduct-precautionary-voluntary-recall-of-Zantac-OTC-in-U-S-and-Canada> (last visited 11/13/19).

The screenshot shows a press release from Sanofi. The title is "Sanofi to conduct precautionary voluntary recall of Zantac OTC in U.S. and Canada". The navigation bar includes links for PRESS RELEASES, FEATURED NEWS, PRESS STATEMENTS, SUBSCRIBE, MEDIA CONTACTS, SOCIAL MEDIA, and PHOTOS & VIDEOS. Below the navigation bar, there are links for RSS, Email page, and Print. The main text of the press release is as follows:

BRIDGEWATER, N.J., Oct. 18, 2019 /PRNewswire/ -- As a precautionary measure, Sanofi will conduct a voluntary recall of Zantac OTC (over-the-counter) in the U.S. and Canada. This recall is being taken due to possible contamination with a nitrosamine impurity called N-nitrosodimethylamine (NDMA). The company is working with health authorities to determine the level and extent of the recall.

On September 13, 2019, the U.S Food and Drug Administration and Health Canada issued public statements alerting that some ranitidine medicines, including Zantac OTC, could contain NDMA at low levels and asked manufacturers to conduct testing.

Evaluations are ongoing on both drug substance (active ingredient) and finished drug product. Due to inconsistencies in preliminary test results of the active ingredient used in the U.S. and Canadian products, Sanofi has made the decision to conduct the voluntary recall in the U.S. and Canada as the investigation continues.

Active ingredients used in Sanofi's ranitidine products outside of the U.S. and Canada are sourced from different suppliers. Sanofi is committed to transparency and will continue to communicate results with health authorities from the ongoing testing, and work with them to make informed decisions based on available data and evidence.

Sanofi encourages anyone using Zantac OTC to speak with their health care providers or pharmacists if they have any additional questions.

70. Sanofi also deemed the recall as “precautionary,” done because of “possible contamination” with an “impurity” called NDMA. It quoted the FDA’s September 13, 2019, Statement -- despite the FDA having found “unacceptable” levels of NDMA in its more recent October 2, 2019 Statement -- and referred to the presence of “NDMA at low levels.”<sup>39</sup>

71. Sanofi claimed that its own testing has resulted in “inconsistencies in preliminary test results of the active ingredient.”<sup>40</sup> Such “inconsistencies” could be interpreted to mean that Sanofi, itself, found NDMA with its recent testing; otherwise, it would have categorically denied the presence of NDMA.

72. Sanofi also criticized Valisure’s testing: “Valisure only showed detectable NDMA after exposing ranitidine to extreme artificial conditions—when they heated ranitidine to 266 degrees Fahrenheit [130 degrees Celsius]...or when they added artificial nitrite far beyond what is

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<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

ordinarily seen in humans.”<sup>41</sup> Sanofi wholly discounted Valisure’s testing, stating that the high levels of NDMA Valisure found were formed “only after exposing ranitidine to extreme artificial conditions.”<sup>42</sup>

**F. FDA Finds that Some Tests Show Unacceptable Levels of NDMA.**

73. On November 1, 2019, the FDA released additional test results for the “contaminant” NDMA.<sup>43</sup> In yet another contradictory statement, the FDA found “levels of NDMA in ranitidine that are similar to the levels you would expect to be exposed to if you ate common foods like grilled or smoked meats.”<sup>44</sup> The FDA noted that the acceptable intake for NDMA is 96 ng, and concluded that its tests showed NDMA at levels lower than those found by third-party scientists (again likely referring to Valisure), but added that its testing nevertheless discovered **“some levels still exceed what the FDA considers acceptable....”**<sup>45</sup>

74. The FDA rejected Valisure’s theory that ranitidine turns into NDMA in the stomach: The FDA conducted tests that simulated what happens to ranitidine after it has been exposed to stomach acids and the environment of the intestines, reporting that NDMA is not formed.<sup>46</sup>

75. Putting aside the debate about Valisure’s testing and methodology, tests such as those conducted by the FDA nevertheless found unacceptable levels of NDMA in ranitidine.

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<sup>41</sup> Lewis, Tanya, “What we Know about the Possible Carcinogen Found in Zantac,” *Scientific American* (10/28/19), found at <https://www.scientificamerican.com/article/what-we-know-about-the-possible-carcinogen-found-in-zantac/> (quoting an email from Sanofi’s spokesperson ) (last visited 11/13/19).

<sup>42</sup> *Id.*

<sup>43</sup> “11/1/19: Press Release – Statement on new testing results, including low levels of impurities in ranitidine drugs,” found at <https://www.fda.gov/news-events/press-announcements/statement-new-testing-results-including-low-levels-impurities-ranitidine-drugs> (last visited 11/13/19).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* (emphasis added).

<sup>46</sup> *Id.*

### **G. Plaintiffs and the Class**

76. For over 32 years, Plaintiff Lynn White purchased and took 150 mg once or twice daily of prescription and over-the-counter Zantac manufactured and sold by the GSK and Sanofi Defendants. Now, based on Valisure's testing and the FDA Statements, Plaintiff is forced to live in constant and nagging fear that she will develop cancer because of her long-term exposure to Zantac – a drug that for all these years was represented to be, and that she believed to be, safe. She has spent thousands of dollars only to put herself at an increased risk for developing various types of cancer, and will be subject to the stresses, costs and expenses of medical and diagnostic monitoring for the rest of her life.

77. The same is true for Plaintiff Nataliya Birman. For most of 2019, she took 150 mg of ranitidine daily manufactured by the Glenmark Defendants or the Dr. Reddy's Defendants. She, too, has put herself at an increased risk for developing various types of cancer, and will be subject to the stresses, costs and expenses of medical and diagnostic monitoring for the rest of her life.

### **CLASS ALLEGATIONS**

78. Plaintiffs bring this action in their individual capacity and on behalf of the following class and state subclasses ("Classes") pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or 23(c)(4):

**Nationwide Class – GlaxoSmithKline:** All individuals in the United States who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, developed and manufactured by the GlaxoSmithKline Defendants and who have not been diagnosed with cancer.

**Breach of Implied Warranty Subclass - GlaxoSmithKline:** All individuals residing in Alaska, Arkansas, Colorado, District of Columbia, Hawaii, Illinois, Louisiana, Michigan, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota,

Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, Vermont, West Virginia, and Wyoming who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the GlaxoSmithKline Defendants and who have not been diagnosed with cancer.

**Nationwide Class – Sanofi:** All individuals in the United States who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Sanofi Defendants and who have not been diagnosed with cancer.

**Breach of Implied Warranty Subclass - Sanofi:** All individuals residing in Alaska, Arkansas, Colorado, District of Columbia, Hawaii, Illinois, Louisiana, Michigan, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, Vermont, West Virginia, and Wyoming who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Sanofi Defendants and who have not been diagnosed with cancer.

**Nationwide Class – Dr. Reddy's:** All individuals in the United States who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Dr. Reddy's Defendants and who have not been diagnosed with cancer.

**Breach of Implied Warranty Subclass – Dr. Reddy's:** All individuals residing in Alaska, Arkansas, Colorado, District of Columbia, Hawaii, Illinois, Louisiana, Michigan, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, Vermont, West Virginia, and Wyoming who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Dr. Reddy's Defendants and who have not been diagnosed with cancer.



**Nationwide Class – Glenmark:** All individuals in the United States who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Glenmark Defendants and who have not been diagnosed with cancer.

**Breach of Implied Warranty Subclass - Glenmark:** All individuals residing in Alaska, Arkansas, Colorado, District of Columbia, Hawaii, Illinois, Louisiana, Michigan, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Texas, Vermont, West Virginia, and Wyoming who, for personal use, took prescription or over-the-counter ranitidine, including Zantac, manufactured by the Glenmark Defendants and who have not been diagnosed with cancer.

79. Excluded from the Classes are Defendants and any of their affiliates, parents, subsidiaries, officers, and directors; any entity in which Defendants have a controlling interest; all persons who make a timely election to be excluded from the class; governmental entities; and all judges assigned to hear any aspect of this litigation, including their immediate family members.

80. Plaintiffs reserve the right to modify or amend the class definitions, including the addition of one or more subclasses, after having the opportunity to conduct discovery.

81. Numerosity: In 2016, Zantac was the 50<sup>th</sup> most prescribed medication in the United States, with 15 million prescriptions reported.<sup>47</sup> This statistic does not capture the over-the-counter sales. As such, the members of the Classes are so numerous that joinder is impractical.

82. Typicality: Plaintiffs' claims are typical of the claims of each class member in that Plaintiffs, like all class members, took prescription and/or over-the-counter ranitidine, including Zantac, and now face an increased risk of developing cancer. Plaintiffs and the class members

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<sup>47</sup> <https://clincalc.com/DrugStats/Top300Drugs.aspx> (last visited 11/14/19).

were injured through Defendants' common course of misconduct, and Plaintiffs are advancing the same legal theories on behalf of themselves and the Classes.

83. Adequacy: Plaintiffs will fairly and adequately protect the interest of the Classes. Plaintiffs' interests and the interests of all other members of the Classes are identical, and Plaintiffs are cognizant of their duty and responsibility to the Classes. Further, the interests of the Nationwide Class are not conflicting or divergent but, rather, are common. Accordingly, Plaintiffs can fairly and adequately represent the interests of the Classes. Moreover, Plaintiffs' counsel are competent and experienced in litigating class actions, including litigation of this kind. Plaintiffs and counsel intend to vigorously prosecute this case and will fairly and adequately protect the Classes' interests.

84. Commonality and Predominance: There are numerous questions of law and fact common to the Classes, and these common questions predominate over any issues affecting only individual class members. Questions common to the class include, but are not limited to:

- a. Whether ranitidine, including Zantac, contains unacceptable levels of NDMA;
- b. Whether ranitidine, including Zantac, increases the risk of developing cancer;
- c. Whether Defendants knew or should have known that ranitidine and/or Zantac contains unacceptable levels of NDMA;
- d. Whether Defendants knew or should have known that ranitidine and/or Zantac increases the risk of developing cancer;
- e. Whether Defendants fraudulently concealed the fact that ranitidine, including Zantac, contains unacceptable levels of NDMA;
- f. Whether Defendants fraudulently concealed the fact that ranitidine, including Zantac, increases the risk of developing cancer;

- g. Whether Defendants misrepresented ranitidine's and/or Zantac's safety in marketing, advertising and promoting it;
- h. Whether Plaintiffs and the class members are entitled to recover as damages the amounts they spent purchasing ranitidine, including Zantac;
- i. Whether Plaintiffs and the class members are entitled to medical monitoring because of their exposure to ranitidine, including Zantac;
- j. Whether Defendants breached implied warranties connected with ranitidine, including Zantac; and
- k. Whether Plaintiffs and class members are entitled relief in the nature of a medical monitoring program.

85. Superiority: A class action is superior to any other available means for the fair and efficient adjudication of this controversy, and no unusual difficulties are likely to be encountered in the management of this class action. The purpose of a class action is to permit litigation against wrongdoers even when damages to an individual plaintiff may not be sufficient to justify individual litigation. Here, because Plaintiffs and the Class have not developed cancer, the damages suffered by them are relatively small as compared to the burden and expense required to individually litigate their claims against Defendants, and thus, individual litigation to redress Defendants' wrongful conduct would be impracticable. Individual litigation by each class member would also strain the court system, create the potential for inconsistent or contradictory judgments, and increase the delay and expense to all parties and the court system. By contrast, the class action presents far fewer management difficulties and provides the benefits of a single adjudication, economies of scale, and comprehensive supervision by a single court.

86. Equitable Relief: Class certification is also appropriate under Rule 23(b)(2) because Defendants have acted and refused to act on grounds generally applicable to the Classes as a whole, such that final injunctive relief is appropriate with respect to the Classes as a whole. Such injunctive relief includes, but is not limited to, the implementation and funding of a medical monitoring program for Plaintiffs and the Class that is sufficient to monitor their health and to ensure the beneficial early detection of diseases, specifically cancers caused by ingesting ranitidine.

87. This action is also properly maintainable under Rule 23(c)(4) in that particular issues common to the class, as set out *supra*, are most appropriately and efficiently resolved via class action, and would advance the disposition of this matter and the parties' interests therein.

**COUNT I: VIOLATION OF STATE CONSUMER PROTECTION ACTS AGAINST  
THE GLAXOSMITHKLINE DEFENDANTS**

88. Plaintiff Lynn White brings Count I on behalf of the Nationwide Class – GlaxoSmithKline against the GlaxoSmithKline Defendants.

89. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

90. Plaintiff bring this count for violations of the state consumer protection acts including:

- a. the Alabama Deceptive Trade Practices Act, Code of Ala. § 8-19-1, et seq.;
- b. the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, et seq.;
- c. the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, et seq.;
- d. the Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, et seq.;
- e. the California Unfair Competition Law, Bus. & Prof. Code §§ 17200, et seq. and 17500, et seq.;

- f. the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
- g. the Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. § 6-1-101, et seq.;
- h. the Connecticut Unfair Trade Practices Act, Conn. Gen Stat. Ann. § 42- 110, et seq.;
- i. the Delaware Consumer Fraud Act, 6 Del. Code § 2513, et seq.;
- j. the D.C. Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.;
- k. the Florida Deceptive And Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.;
- l. the Georgia Fair Business Practices Act, Ga. Code Ann. § 10-1-390, et seq.;
- m. the Hawaii Unfair Competition Law, Haw. Rev. Stat. § 480-2, et seq.;
- n. the Idaho Consumer Protection Act, Idaho Code. Ann. § 48-601, et seq.;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 501/1, et seq.;
- p. the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-2, et seq.;
- q. Iowa's Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.3;
- r. the Kansas Consumer Protection Act, Kan. Stat. Ann. § 50-623, et seq.;
- s. the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, et seq.;
- t. the Louisiana Unfair Trade Practices And Consumer Protection Law, LSA-R.S. 51:1401, et seq.;
- u. the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.;
- v. the Maryland Consumer Protection Act, Md. Code Ann. Com. Law, § 13-301, et seq.;

- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, Mass. Gen Laws Ann. Ch. 93A, et seq.;
- x. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq.;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F, et seq.;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.;
- aa. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq.;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act, M.C.A. § 30-14-101 et seq.;
- cc. the Nebraska Consumer Protection Act, Neb. Rev. St. §§ 59-1601, et seq.;
- dd. the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 41.600, et seq.;
- ee. the New Hampshire Regulation of Business Practices For Consumer Protection, N.H. Rev. Stat. § 358-A:1, et seq.;
- ff. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8, et seq.;
- gg. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, et seq.;
- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, et seq.;
- ii. the North Carolina Unfair And Deceptive Trade Practices Act, N.C. Gen Stat. § 75-1.1, et seq.;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15, et seq.;
- kk. the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, et seq.;
- ll. the Oklahoma Consumer Protection Act, Okla. Stat. tit. 15 § 751, et seq.;

- mm. the Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605, et seq.;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, et seq.;
- oo. the Rhode Island Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-5.2(B), et seq.;
- pp. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5- 10, et seq.;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection, S.D. Codified Laws § 37-24-1, et seq.;
- rr. the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq.;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, et seq.;
- tt. the Utah Consumer Sales Practices Act, Utah Code. Ann. § 13-11-175, et seq.;
- uu. the Vermont Consumer Fraud Act, 9 V.S.A. § 2451, et seq.;
- vv. the Virginia Consumer Protection Act of 1977, Va. Code Ann. § 59.1-199, et seq.;
- ww. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq.;
- xx. the West Virginia Consumer Credit And Protection Act, W. Va. Code § 46A, et seq.;
- yy. the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq.; and
- zz. the Wyoming Consumer Protection Act, Wyo. Stat. Ann. § 40-12-101, et seq.

91. Plaintiff has provided Defendants with notice of their violations of Code of Ala. § 8-19-10, Alaska Stat. § 45.50.535, Cal. Civ. Code § 1782(a), Ga. Code Ann. § 10-1-399, 815 ILCS 505/10a, Ind. Code Ann. § 24-5-0.5-5, Me. Rev. Stat. Ann. Tit. 5, § 213, Mass. Gen Laws Ann. Ch. 93A, Miss. Code Ann. § 75-24-15, Tex. Bus. & Com. Code § 17.505, W. Va. Code § 46A-6-106, Wyo. Stat. § 40-12-109, and any other state consumer protection statute requiring notice to them of a claim for damages. The notice was transmitted on the day this lawsuit was filed. Plaintiffs initially bring a claim for injunctive or equitable relief under these particular statutes. After the respective cure periods have expired and Defendants have failed to adequately address the violations alleged herein, Plaintiff will amend the complaint to add a claim for damages under the respective statutes.

92. The acts, practices, misrepresentations and omissions by Defendants described above, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

93. Defendants violated the above-enumerated statutes by, among other things, willfully ignoring or concealing scientific evidence regarding ranitidine's, including Zantac's, dangerous properties, consciously failing to disclose information regarding the relationship between Zantac and NDMA and cancer, and making knowing and intentional statements and misrepresentations about the safety of Zantac, all of which were material, false, and/or misleading.

94. Defendants knew or should have known that their conduct violated the above-enumerated statutes.

95. Defendants intended that Plaintiff and the Nationwide Class would rely on their misrepresentations, omissions, and concealment and purchase ranitidine, including Zantac.



96. Had Defendants disclosed all available material information regarding ranitidine, including Zantac, Plaintiff and the Nationwide Class would not have purchased it.

97. The foregoing acts, omissions, and practices proximately caused Plaintiff and the Nationwide Class members to suffer damages, including but not limited to the amount of moneys each spent purchasing ranitidine, including Zantac.

98. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

99. Plaintiff and the Nationwide Class also seek any and all equitable relief to which they are entitled under the above-enumerated statutes, including but not limited to the implementation and funding of a medical monitoring program.

100. Plaintiff and the Nationwide Class also seek treble damages and attorneys' fees and costs to which they are entitled under the above-enumerated statutes.

**COUNT II: VIOLATION OF STATE CONSUMER PROTECTION ACTS AGAINST  
THE SANOFI DEFENDANTS**

101. Plaintiff Lynn White brings Count II on behalf of the Nationwide Class - Sanofi against the Sanofi Defendants.

102. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

103. Plaintiff bring this count for violations of the state consumer protection acts including:

a. the Alabama Deceptive Trade Practices Act, Code of Ala. § 8-19-1, et seq.;

104.

- b. the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, et seq.;
- c. the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, et seq.;
- d. the Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, et seq.;
- e. the California Unfair Competition Law, Bus. & Prof. Code §§ 17200, et seq. and 17500, et seq.;
- f. the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
- g. the Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. § 6-1-101, et seq.;
- h. the Connecticut Unfair Trade Practices Act, Conn. Gen Stat. Ann. § 42- 110, et seq.;
- i. the Delaware Consumer Fraud Act, 6 Del. Code § 2513, et seq.;
- j. the D.C. Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.;
- k. the Florida Deceptive And Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.;
- l. the Georgia Fair Business Practices Act, Ga. Code Ann. § 10-1-390, et seq.;
- m. the Hawaii Unfair Competition Law, Haw. Rev. Stat. § 480-2, et seq.;
- n. the Idaho Consumer Protection Act, Idaho Code. Ann. § 48-601, et seq.;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 501/1, et seq.;
- p. the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-2, et seq.;
- q. Iowa's Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.3;
- r. the Kansas Consumer Protection Act, Kan. Stat. Ann. § 50-623, et seq.;

- s. the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, et seq.;
- t. the Louisiana Unfair Trade Practices And Consumer Protection Law, LSA-R.S. 51:1401, et seq.;
- u. the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.;
- v. the Maryland Consumer Protection Act, Md. Code Ann. Com. Law, § 13-301, et seq.;
- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, Mass. Gen Laws Ann. Ch. 93A, et seq.;
- x. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq.;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F, et seq.;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.;
- aa. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq.;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act, M.C.A. § 30-14-101 et seq.;
- cc. the Nebraska Consumer Protection Act, Neb. Rev. St. §§ 59-1601, et seq.;
- dd. the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 41.600, et seq.;
- ee. the New Hampshire Regulation of Business Practices For Consumer Protection, N.H. Rev. Stat. § 358-A:1, et seq.;
- ff. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8, et seq.;
- gg. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, et seq.;
- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, et seq.;

- ii. the North Carolina Unfair And Deceptive Trade Practices Act, N.C. Gen Stat. § 75-1.1, et seq.;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15, et seq.;
- kk. the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, et seq.;
- ll. the Oklahoma Consumer Protection Act, Okla. Stat. tit. 15 § 751, et seq.;
- mm. the Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605, et seq.;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, et seq.;
- oo. the Rhode Island Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-5.2(B), et seq.;
- pp. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5- 10, et seq.;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection, S.D. Codified Laws § 37-24-1, et seq.;
- rr. the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq.;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, et seq.;
- tt. the Utah Consumer Sales Practices Act, Utah Code. Ann. § 13-11-175, et seq.;
- uu. the Vermont Consumer Fraud Act, 9 V.S.A. § 2451, et seq.;
- vv. the Virginia Consumer Protection Act of 1977, Va. Code Ann. § 59.1-199, et seq.;
- ww. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq.;

xx. the West Virginia Consumer Credit And Protection Act, W. Va. Code § 46A, et seq.;

yy. the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq.; and

zz. the Wyoming Consumer Protection Act, Wyo. Stat. Ann. § 40-12-101, et seq.

105. Plaintiff has provided Defendants with notice of their violations of Code of Ala. § 8-19-10, Alaska Stat. § 45.50.535, Cal. Civ. Code § 1782(a), Ga. Code Ann. § 10-1-399, 815 ILCS 505/10a, Ind. Code Ann. § 24-5-0.5-5, Me. Rev. Stat. Ann. Tit. 5, § 213, Mass. Gen Laws Ann. Ch. 93A, Miss. Code Ann. § 75-24-15, Tex. Bus. & Com. Code § 17.505, W. Va. Code § 46A-6-106, Wyo. Stat. § 40-12-109, and any other state consumer protection statute requiring notice to them of a claim for damages. The notice was transmitted on the day this lawsuit was filed. Plaintiffs initially bring a claim for injunctive or equitable relief under these particular statutes. After the respective cure periods have expired and Defendants have failed to adequately address the violations alleged herein, Plaintiff will amend the complaint to add a claim for damages under the respective statutes.

106. The acts, practices, misrepresentations and omissions by Defendants described above, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

107. Defendants violated the above-enumerated statutes by, among other things, willfully ignoring or concealing scientific evidence regarding ranitidine's, including Zantac's, dangerous properties, consciously failing to disclose information regarding the relationship between Zantac and NDMA and cancer, and making knowing and intentional statements and misrepresentations about the safety of Zantac, all of which were material, false, and/or misleading.

108. Defendants knew or should have known that their conduct violated the above-enumerated statutes.

109. Defendants intended that Plaintiff and the Nationwide Class would rely on their misrepresentations, omissions, and concealment and purchase ranitidine, including Zantac.

110. Had Defendants disclosed all available material information regarding ranitidine, including Zantac, Plaintiff and the Nationwide Class would not have purchased it.

111. The foregoing acts, omissions, and practices proximately caused Plaintiff and the Nationwide Class members to suffer damages, including but not limited to the amount of moneys each spent purchasing ranitidine, including Zantac.

112. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

113. Plaintiff and the Nationwide Class also seek any and all equitable relief to which they are entitled under the above-enumerated statutes, including but not limited to the implementation and funding of a medical monitoring program.

114. Plaintiff and the Nationwide Class also seek treble damages and attorneys' fees and costs to which they are entitled under the above-enumerated statutes.

**COUNT III: VIOLATION OF STATE CONSUMER PROTECTION ACTS AGAINST  
THE DR. REDDY'S DEFENDANTS**

115. Plaintiff Nataliya Berman brings Count III on behalf of the Nationwide Class – Dr. Reddy's against the Dr. Reddy's Defendants.

116. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

117. Plaintiff bring this count for violations of the state consumer protection acts including:

- a. the Alabama Deceptive Trade Practices Act, Code of Ala. § 8-19-1, et seq.;
- b. the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, et seq.;
- c. the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, et seq.;
- d. the Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, et seq.;
- e. the California Unfair Competition Law, Bus. & Prof. Code §§ 17200, et seq. and 17500, et seq.;
- f. the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
- g. the Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. § 6-1-101, et seq.;
- h. the Connecticut Unfair Trade Practices Act, Conn. Gen Stat. Ann. § 42- 110, et seq.;
- i. the Delaware Consumer Fraud Act, 6 Del. Code § 2513, et seq.;
- j. the D.C. Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.;
- k. the Florida Deceptive And Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.;
- l. the Georgia Fair Business Practices Act, Ga. Code Ann. § 10-1-390, et seq.;
- m. the Hawaii Unfair Competition Law, Haw. Rev. Stat. § 480-2, et seq.;
- n. the Idaho Consumer Protection Act, Idaho Code. Ann. § 48-601, et seq.;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 501/1, et seq.;
- p. the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-2, et seq.;
- q. Iowa's Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.3;

- r. the Kansas Consumer Protection Act, Kan. Stat. Ann. § 50-623, et seq.;
- s. the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, et seq.;
- t. the Louisiana Unfair Trade Practices And Consumer Protection Law, LSA-R.S. 51:1401, et seq.;
- u. the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.;
- v. the Maryland Consumer Protection Act, Md. Code Ann. Com. Law, § 13-301, et seq.;
- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, Mass. Gen Laws Ann. Ch. 93A, et seq.;
- x. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq.;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F, et seq.;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.;
- aa. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq.;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act, M.C.A. § 30-14-101 et seq.;
- cc. the Nebraska Consumer Protection Act, Neb. Rev. St. §§ 59-1601, et seq.;
- dd. the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 41.600, et seq.;
- ee. the New Hampshire Regulation of Business Practices For Consumer Protection, N.H. Rev. Stat. § 358-A:1, et seq.;
- ff. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8, et seq.;
- gg. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, et seq.;



- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, et seq.;
- ii. the North Carolina Unfair And Deceptive Trade Practices Act, N.C. Gen Stat. § 75-1.1, et seq.;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15, et seq.;
- kk. the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, et seq.;
- ll. the Oklahoma Consumer Protection Act, Okla. Stat. tit. 15 § 751, et seq.;
- mm. the Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605, et seq.;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, et seq.;
- oo. the Rhode Island Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-5.2(B), et seq.;
- pp. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5- 10, et seq.;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection, S.D. Codified Laws § 37-24-1, et seq.;
- rr. the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq.;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, et seq.;
- tt. the Utah Consumer Sales Practices Act, Utah Code. Ann. § 13-11-175, et seq.;
- uu. the Vermont Consumer Fraud Act, 9 V.S.A. § 2451, et seq.;
- vv. the Virginia Consumer Protection Act of 1977, Va. Code Ann. § 59.1-199, et seq.;

ww. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq.;

xx. the West Virginia Consumer Credit And Protection Act, W. Va. Code § 46A, et seq.;

yy. the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq.; and

zz. the Wyoming Consumer Protection Act, Wyo. Stat. Ann. § 40-12-101, et seq.

118. Plaintiff has provided Defendants with notice of their violations of Code of Ala. § 8-19-10, Alaska Stat. § 45.50.535, Cal. Civ. Code § 1782(a), Ga. Code Ann. § 10-1-399, 815 ILCS 505/10a, Ind. Code Ann. § 24-5-0.5-5, Me. Rev. Stat. Ann. Tit. 5, § 213, Mass. Gen Laws Ann. Ch. 93A, Miss. Code Ann. § 75-24-15, Tex. Bus. & Com. Code § 17.505, W. Va. Code § 46A-6-106, Wyo. Stat. § 40-12-109, and any other state consumer protection statute requiring notice to them of a claim for damages. The notice was transmitted on the day this lawsuit was filed. Plaintiffs initially bring a claim for injunctive or equitable relief under these particular statutes. After the respective cure periods have expired and Defendants have failed to adequately address the violations alleged herein, Plaintiff will amend the complaint to add a claim for damages under the respective statutes.

119. The acts, practices, misrepresentations and omissions by Defendants described above, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

120. Defendants violated the above-enumerated statutes by, among other things, willfully ignoring or concealing scientific evidence regarding ranitidine's, including Zantac's, dangerous properties, consciously failing to disclose information regarding the relationship

between Zantac and NDMA and cancer, and making knowing and intentional statements and misrepresentations about the safety of Zantac, all of which were material, false, and/or misleading.

121. Defendants knew or should have known that their conduct violated the above-enumerated statutes.

122. Defendants intended that Plaintiff and the Nationwide Class would rely on their misrepresentations, omissions, and concealment and purchase ranitidine, including Zantac.

123. Had Defendants disclosed all available material information regarding ranitidine, including Zantac, Plaintiff and the Nationwide Class would not have purchased it.

124. The foregoing acts, omissions, and practices proximately caused Plaintiff and the Nationwide Class members to suffer damages, including but not limited to the amount of moneys each spent purchasing ranitidine, including Zantac.

125. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

126. Plaintiff and the Nationwide Class also seek any and all equitable relief to which they are entitled under the above-enumerated statutes, including but not limited to the implementation and funding of a medical monitoring program.

127. Plaintiff and the Nationwide Class also seek treble damages and attorneys' fees and costs to which they are entitled under the above-enumerated statutes.

**COUNT IV: VIOLATION OF STATE CONSUMER PROTECTION ACTS AGAINST  
THE GLENMARK DEFENDANTS**

128. Plaintiff Nataliya Berman brings Count IV on behalf of the Nationwide Class – Glenmark against the Glenmark Defendants.

129. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

130. Plaintiff bring this count for violations of the state consumer protection acts including:

- a. the Alabama Deceptive Trade Practices Act, Code of Ala. § 8-19-1, et seq.;
- b. the Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Stat. § 45.50.471, et seq.;
- c. the Arizona Consumer Fraud Act, Ariz. Rev. Stat. §§ 44-1521, et seq.;
- d. the Arkansas Deceptive Trade Practices Act, Ark. Code § 4-88-101, et seq.;
- e. the California Unfair Competition Law, Bus. & Prof. Code §§ 17200, et seq. and 17500, et seq.;
- f. the California Consumers Legal Remedies Act, Cal. Civ. Code § 1750, et seq.;
- g. the Colorado Consumer Protection Act, Colo. Rev. Stat. Ann. § 6-1-101, et seq.;
- h. the Connecticut Unfair Trade Practices Act, Conn. Gen Stat. Ann. § 42- 110, et seq.;
- i. the Delaware Consumer Fraud Act, 6 Del. Code § 2513, et seq.;
- j. the D.C. Consumer Protection Procedures Act, D.C. Code § 28-3901, et seq.;
- k. the Florida Deceptive And Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, et seq.;
- l. the Georgia Fair Business Practices Act, Ga. Code Ann. § 10-1-390, et seq.;
- m. the Hawaii Unfair Competition Law, Haw. Rev. Stat. § 480-2, et seq.;
- n. the Idaho Consumer Protection Act, Idaho Code. Ann. § 48-601, et seq.;
- o. the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 501/1, et seq.;
- p. the Indiana Deceptive Consumer Sales Act, Ind. Code § 24-5-0.5-2, et seq.;

- q. Iowa's Private Right of Action for Consumer Frauds Act, Iowa Code Ann. § 714H.3;
- r. the Kansas Consumer Protection Act, Kan. Stat. Ann. § 50-623, et seq.;
- s. the Kentucky Consumer Protection Act, Ky. Rev. Stat. Ann. § 367.110, et seq.;
- t. the Louisiana Unfair Trade Practices And Consumer Protection Law, LSA-R.S. 51:1401, et seq.;
- u. the Maine Unfair Trade Practices Act, Me. Rev. Stat. Ann. Tit. 5, § 207, et seq.;
- v. the Maryland Consumer Protection Act, Md. Code Ann. Com. Law, § 13-301, et seq.;
- w. the Massachusetts Regulation of Business Practices for Consumers Protection Act, Mass. Gen Laws Ann. Ch. 93A, et seq.;
- x. the Michigan Consumer Protection Act, Mich. Comp. Laws Ann. § 445.901, et seq.;
- y. the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F, et seq.;
- z. the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1 et seq.;
- aa. the Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407, et seq.;
- bb. the Montana Unfair Trade Practices and Consumer Protection Act, M.C.A. § 30-14-101 et seq.;
- cc. the Nebraska Consumer Protection Act, Neb. Rev. St. §§ 59-1601, et seq.;
- dd. the Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 41.600, et seq.;
- ee. the New Hampshire Regulation of Business Practices For Consumer Protection, N.H. Rev. Stat. § 358-A:1, et seq.;
- ff. the New Jersey Consumer Fraud Act, N.J. Stat. Ann. § 56:8, et seq.;

- gg. the New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, et seq.;
- hh. the New York Consumer Protection from Deceptive Acts and Practices, N.Y. Gen. Bus. Law § 349, et seq.;
- ii. the North Carolina Unfair And Deceptive Trade Practices Act, N.C. Gen Stat. § 75-1.1, et seq.;
- jj. the North Dakota Consumer Fraud Act, N.D. Cent. Code § 51-15, et seq.;
- kk. the Ohio Consumer Sales Practices Act, Ohio Rev. Code Ann. § 1345.01, et seq.;
- ll. the Oklahoma Consumer Protection Act, Okla. Stat. tit. 15 § 751, et seq.;
- mm. the Oregon Unlawful Trade Practices Act, Or. Rev. Stat. § 646.605, et seq.;
- nn. the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1, et seq.;
- oo. the Rhode Island Deceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1-5.2(B), et seq.;
- pp. the South Carolina Unfair Trade Practices Act, S.C. Code Ann. §§ 39-5- 10, et seq.;
- qq. the South Dakota Deceptive Trade Practices and Consumer Protection, S.D. Codified Laws § 37-24-1, et seq.;
- rr. the Tennessee Consumer Protection Act, Tenn. Code Ann. § 47-18-101, et seq.;
- ss. the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code § 17.41, et seq.;
- tt. the Utah Consumer Sales Practices Act, Utah Code. Ann. § 13-11-175, et seq.;
- uu. the Vermont Consumer Fraud Act, 9 V.S.A. § 2451, et seq.;

vv. the Virginia Consumer Protection Act of 1977, Va. Code Ann. § 59.1-199, et seq.;

ww. the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.010, et seq.;

xx. the West Virginia Consumer Credit And Protection Act, W. Va. Code § 46A, et seq.;

yy. the Wisconsin Deceptive Trade Practices Act, Wis. Stat. § 100.18, et seq.; and

zz. the Wyoming Consumer Protection Act, Wyo. Stat. Ann. § 40-12-101, et seq.

131. Plaintiff has provided Defendants with notice of their violations of Code of Ala. § 8-19-10, Alaska Stat. § 45.50.535, Cal. Civ. Code § 1782(a), Ga. Code Ann. § 10-1-399, 815 ILCS 505/10a, Ind. Code Ann. § 24-5-0.5-5, Me. Rev. Stat. Ann. Tit. 5, § 213, Mass. Gen Laws Ann. Ch. 93A, Miss. Code Ann. § 75-24-15, Tex. Bus. & Com. Code § 17.505, W. Va. Code § 46A-6-106, Wyo. Stat. § 40-12-109, and any other state consumer protection statute requiring notice to them of a claim for damages. The notice was transmitted on the day this lawsuit was filed. Plaintiffs initially bring a claim for injunctive or equitable relief under these particular statutes. After the respective cure periods have expired and Defendants have failed to adequately address the violations alleged herein, Plaintiff will amend the complaint to add a claim for damages under the respective statutes.

132. The acts, practices, misrepresentations and omissions by Defendants described above, occurring in the course of conduct involving trade or commerce, constitute unfair methods of competition and unfair or deceptive acts or practices within the meaning of each of the above-enumerated statutes.

133. Defendants violated the above-enumerated statutes by, among other things, willfully ignoring or concealing scientific evidence regarding ranitidine's, including Zantac's,

dangerous properties, consciously failing to disclose information regarding the relationship between Zantac and NDMA and cancer, and making knowing and intentional statements and misrepresentations about the safety of Zantac, all of which were material, false, and/or misleading.

134. Defendants knew or should have known that their conduct violated the above-enumerated statutes.

135. Defendants intended that Plaintiff and the Nationwide Class would rely on their misrepresentations, omissions, and concealment and purchase ranitidine, including Zantac.

136. Had Defendants disclosed all available material information regarding ranitidine, including Zantac, Plaintiff and the Nationwide Class would not have purchased it.

137. The foregoing acts, omissions, and practices proximately caused Plaintiff and the Nationwide Class members to suffer damages, including but not limited to the amount of moneys each spent purchasing ranitidine, including Zantac.

138. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

139. Plaintiff and the Nationwide Class also seek any and all equitable relief to which they are entitled under the above-enumerated statutes, including but not limited to the implementation and funding of a medical monitoring program.

140. Plaintiff and the Nationwide Class also seek treble damages and attorneys' fees and costs to which they are entitled under the above-enumerated statutes.

**COUNT V: BREACH OF IMPLIED WARRANTIES AGAINST THE  
GLAXOSMITHKLINE DEFENDANTS**

141. Plaintiff incorporates by reference all preceding and subsequent paragraphs.



142. This claim for breach of implied warranties is brought by Plaintiff Lynn White on behalf of herself and the Breach of Implied Warranty Subclass – GlaxoSmithKline for violations of the following statutes:

- a. Alaska Stat. § 45.02.314;
- b. Ark. Code. Ann. § 4-2-314;
- c. Colo. Rev. Stat. § 4-2-314;
- d. D.C. Code. § 28:2-314;
- e. Haw. Rev. Stat. § 490:2-314;
- f. 810 ILCS 5/1-101, et seq. (for purposes of non-economic damages);
- g. La. Civ. Code Ann. Art. § 2520;
- h. MCL § 440.2314;
- i. Mont. Code Ann. § 30-2-314;
- j. Neb. U.C.C. § 2-314;
- k. Nev. Rev. Stat. U.C.C. § 104.2314;
- l. N.H. Rev. Ann. § 382-A:2-314;
- m. N.J. Stat. Ann. § 12A:2-314;
- n. N.M. Stat. Ann. § 55-2-314;
- o. N.D. Stat. § 41-02-314;
- p. Okla. Stat. tit. 12A § 2-314;
- q. 13 Pa. C.S. § 2314;
- r. R.I. Gen. Laws § 6A-2-314;
- s. S.D. Stat. § 57A-2-314;
- t. Tex. Bus. & Com. Code Ann. § 2-314;
- u. Vt. Stat. Ann. 9A § 2-314;

v. W. Va. Code § 46-2-314;

w. Wyo. Stat. § 34.1-2-314.

143. Plaintiff has provided Defendants with notice of their breach of implied warranties under any states where such notice is required. The notice was transmitted on the day this lawsuit was filed.

144. During the relevant times set out above, Defendants were manufacturers of ranitidine, including Zantac.

145. Under the above statutes, a warranty of merchantability is implied in every contract for the sale of goods. The above states' provisions do not require privity between Plaintiff and Defendants and/or do not require privity for non-economic damages such as medical monitoring.

146. A warranty of fitness for a particular purpose is implied where the seller knows the purpose for which the goods are required and the buyer is relying on the seller's skill or judgment to furnish suitable goods.

147. All during the time Defendants were respectively manufacturing, marketing, and selling ranitidine, including Zantac, Defendants knew of the uses for which ranitidine, including Zantac, was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

148. The implied warranties of merchantability and fitness run from Defendants to consumers, like Plaintiffs and the Breach of Implied Warranty Subclass.

149. Defendants' representations and warranties were false, misleading, and inaccurate in that ranitidine, including Zantac, was unsafe, unreasonably dangerous, defective, not of merchantable quality, and unfit for the ordinary purpose for which it is intended.

150. Defendants knew or had reason to know of these material facts, and wrongfully and fraudulently concealed these material facts from Plaintiff and the Breach of Implied Warranty Subclass. Plaintiffs and the Breach of Implied Warranty Subclass were induced to purchase and ingest ranitidine, including Zantac, under false or fraudulent pretenses.

151. Had Defendants disclosed all material information regarding ranitidine, including Zantac, described above, Plaintiff and the Breach of Implied Warranty Subclass would not have purchased and consumed Zantac.

152. Plaintiff and the Breach of Implied Warranty Subclass reasonably relied on Defendants' skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

153. Defendants knew or had reason to know that Plaintiff and the Breach of Implied Warranty Subclass would rely on Defendants' skill and judgment.

154. Defendants' breach of implied warranties proximately caused Plaintiff and the Breach of Implied Warranty Subclass members to suffer damages.

155. Plaintiffs and the Breach of Implied Warranty Subclass seek compensatory damages, attorneys' fees and costs, in addition any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

**COUNT VI: BREACH OF IMPLIED WARRANTIES AGAINST THE SANOFI  
DEFENDANTS**

156. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

157. This claim for breach of implied warranties is brought by Plaintiff Lynn White on behalf of herself and the Breach of Implied Warranty Subclass – Sanofi for violations of the following statutes:

- a. Alaska Stat. § 45.02.314;
- b. Ark. Code. Ann. § 4-2-314;
- c. Colo. Rev. Stat. § 4-2-314;
- d. D.C. Code. § 28:2-314;
- e. Haw. Rev. Stat. § 490:2-314;
- f. 810 ILCS 5/1-101, et seq. (for purposes of non-economic damages);
- g. La. Civ. Code Ann. Art. § 2520;
- h. MCL § 440.2314;
- i. Mont. Code Ann. § 30-2-314;
- j. Neb. U.C.C. § 2-314;
- k. Nev. Rev. Stat. U.C.C. § 104.2314;
- l. N.H. Rev. Ann. § 382-A:2-314;
- m. N.J. Stat. Ann. § 12A:2-314;
- n. N.M. Stat. Ann. § 55-2-314;
- o. N.D. Stat. § 41-02-314;
- p. Okla. Stat. tit. 12A § 2-314;
- q. 13 Pa. C.S. § 2314;
- r. R.I. Gen. Laws § 6A-2-314;
- s. S.D. Stat. § 57A-2-314;
- t. Tex. Bus. & Com. Code Ann. § 2-314;
- u. Vt. Stat. Ann. 9A § 2-314;
- v. W. Va. Code § 46-2-314;
- w. Wyo. Stat. § 34.1-2-314.

158. Plaintiff has provided Defendants with notice of their breach of implied warranties under any states where such notice is required. The notice was transmitted on the day this lawsuit was filed.

159. During the relevant times set out above, Defendants were manufacturers of ranitidine, including Zantac.

160. Under the above statutes, a warranty of merchantability is implied in every contract for the sale of goods. The above states' provisions do not require privity between Plaintiff and Defendants and/or do not require privity for non-economic damages such as medical monitoring.

161. A warranty of fitness for a particular purpose is implied where the seller knows the purpose for which the goods are required and the buyer is relying on the seller's skill or judgment to furnish suitable goods.

162. All during the time Defendants were respectively manufacturing, marketing, and selling ranitidine, including Zantac, Defendants knew of the uses for which ranitidine, including Zantac, was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

163. The implied warranties of merchantability and fitness run from Defendants to consumers, like Plaintiffs and the Breach of Implied Warranty Subclass.

164. Defendants' representations and warranties were false, misleading, and inaccurate in that ranitidine, including Zantac, was unsafe, unreasonably dangerous, defective, not of merchantable quality, and unfit for the ordinary purpose for which it is intended.

165. Defendants knew or had reason to know of these material facts, and wrongfully and fraudulently concealed these material facts from Plaintiff and the Breach of Implied Warranty

Subclass. Plaintiffs and the Breach of Implied Warranty Subclass were induced to purchase and ingest ranitidine, including Zantac, under false or fraudulent pretenses.

166. Had Defendants disclosed all material information regarding ranitidine, including Zantac, described above, Plaintiff and the Breach of Implied Warranty Subclass would not have purchased and consumed Zantac.

167. Plaintiff and the Breach of Implied Warranty Subclass reasonably relied on Defendants' skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

168. Defendants knew or had reason to know that Plaintiff and the Breach of Implied Warranty Subclass would rely on Defendants' skill and judgment.

169. Defendants' breach of implied warranties proximately caused Plaintiff and the Breach of Implied Warranty Subclass members to suffer damages.

170. Plaintiffs and the Breach of Implied Warranty Subclass seek compensatory damages, attorneys' fees and costs, in addition any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

**COUNT VII: BREACH OF IMPLIED WARRANTIES AGAINST THE DR. REDDY'S DEFENDANTS**

171. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

172. This claim for breach of implied warranties is brought by Plaintiff Nataliya Birman on behalf of herself and the Breach of Implied Warranty Subclass – Dr. Reddy's for violations of the following statutes:

- a. Alaska Stat. § 45.02.314;
- b. Ark. Code. Ann. § 4-2-314;

- c. Colo. Rev. Stat. § 4-2-314;
- d. D.C. Code. § 28:2-314;
- e. Haw. Rev. Stat. § 490:2-314;
- f. 810 ILCS 5/1-101, et seq. (for purposes of non-economic damages);
- g. La. Civ. Code Ann. Art. § 2520;
- h. MCL § 440.2314;
- i. Mont. Code Ann. § 30-2-314;
- j. Neb. U.C.C. § 2-314;
- k. Nev. Rev. Stat. U.C.C. § 104.2314;
- l. N.H. Rev. Ann. § 382-A:2-314;
- m. N.J. Stat. Ann. § 12A:2-314;
- n. N.M. Stat. Ann. § 55-2-314;
- o. N.D. Stat. § 41-02-314;
- p. Okla. Stat. tit. 12A § 2-314;
- q. 13 Pa. C.S. § 2314;
- r. R.I. Gen. Laws § 6A-2-314;
- s. S.D. Stat. § 57A-2-314;
- t. Tex. Bus. & Com. Code Ann. § 2-314;
- u. Vt. Stat. Ann. 9A § 2-314;
- v. W. Va. Code § 46-2-314;
- w. Wyo. Stat. § 34.1-2-314.

173. Plaintiff has provided Defendants with notice of their breach of implied warranties under any states where such notice is required. The notice was transmitted on the day this lawsuit was filed.

174. During the relevant times set out above, Defendants were manufacturers of ranitidine, including Zantac.

175. Under the above statutes, a warranty of merchantability is implied in every contract for the sale of goods. The above states' provisions do not require privity between Plaintiff and Defendants and/or do not require privity for non-economic damages such as medical monitoring.

176. A warranty of fitness for a particular purpose is implied where the seller knows the purpose for which the goods are required and the buyer is relying on the seller's skill or judgment to furnish suitable goods.

177. All during the time Defendants were respectively manufacturing, marketing, and selling ranitidine, including Zantac, Defendants knew of the uses for which ranitidine, including Zantac, was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

178. The implied warranties of merchantability and fitness run from Defendants to consumers, like Plaintiffs and the Breach of Implied Warranty Subclass.

179. Defendants' representations and warranties were false, misleading, and inaccurate in that ranitidine, including Zantac, was unsafe, unreasonably dangerous, defective, not of merchantable quality, and unfit for the ordinary purpose for which it is intended.

180. Defendants knew or had reason to know of these material facts, and wrongfully and fraudulently concealed these material facts from Plaintiff and the Breach of Implied Warranty Subclass. Plaintiffs and the Breach of Implied Warranty Subclass were induced to purchase and ingest ranitidine, including Zantac, under false or fraudulent pretenses.



181. Had Defendants disclosed all material information regarding ranitidine, including Zantac, described above, Plaintiff and the Breach of Implied Warranty Subclass would not have purchased and consumed Zantac.

182. Plaintiff and the Breach of Implied Warranty Subclass reasonably relied on Defendants' skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

183. Defendants knew or had reason to know that Plaintiff and the Breach of Implied Warranty Subclass would rely on Defendants' skill and judgment.

184. Defendants' breach of implied warranties proximately caused Plaintiff and the Breach of Implied Warranty Subclass members to suffer damages.

185. Plaintiffs and the Breach of Implied Warranty Subclass seek compensatory damages, attorneys' fees and costs, in addition any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

**COUNT VIII: BREACH OF IMPLIED WARRANTIES AGAINST THE  
GLENMARK DEFENDANTS**

186. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

187. This claim for breach of implied warranties is brought by Plaintiff Nataliya Berman on behalf of herself and the Breach of Implied Warranty Subclass – Glenmark for violations of the following statutes:

- a. Alaska Stat. § 45.02.314;
- b. Ark. Code. Ann. § 4-2-314;
- c. Colo. Rev. Stat. § 4-2-314;
- d. D.C. Code. § 28:2-314;

- e. Haw. Rev. Stat. § 490:2-314;
- f. 810 ILCS 5/1-101, et seq. (for purposes of non-economic damages);
- g. La. Civ. Code Ann. Art. § 2520;
- h. MCL § 440.2314;
- i. Mont. Code Ann. § 30-2-314;
- j. Neb. U.C.C. § 2-314;
- k. Nev. Rev. Stat. U.C.C. § 104.2314;
- l. N.H. Rev. Ann. § 382-A:2-314;
- m. N.J. Stat. Ann. § 12A:2-314;
- n. N.M. Stat. Ann. § 55-2-314;
- o. N.D. Stat. § 41-02-314;
- p. Okla. Stat. tit. 12A § 2-314;
- q. 13 Pa. C.S. § 2314;
- r. R.I. Gen. Laws § 6A-2-314;
- s. S.D. Stat. § 57A-2-314;
- t. Tex. Bus. & Com. Code Ann. § 2-314;
- u. Vt. Stat. Ann. 9A § 2-314;
- v. W. Va. Code § 46-2-314;
- w. Wyo. Stat. § 34.1-2-314.

188. Plaintiff has provided Defendants with notice of their breach of implied warranties under any states where such notice is required. The notice was transmitted on the day this lawsuit was filed.

189. During the relevant times set out above, Defendants were manufacturers of ranitidine, including Zantac.

190. Under the above statutes, a warranty of merchantability is implied in every contract for the sale of goods. The above states' provisions do not require privity between Plaintiff and Defendants and/or do not require privity for non-economic damages such as medical monitoring.

191. A warranty of fitness for a particular purpose is implied where the seller knows the purpose for which the goods are required and the buyer is relying on the seller's skill or judgment to furnish suitable goods.

192. All during the time Defendants were respectively manufacturing, marketing, and selling ranitidine, including Zantac, Defendants knew of the uses for which ranitidine, including Zantac, was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

193. The implied warranties of merchantability and fitness run from Defendants to consumers, like Plaintiffs and the Breach of Implied Warranty Subclass.

194. Defendants' representations and warranties were false, misleading, and inaccurate in that ranitidine, including Zantac, was unsafe, unreasonably dangerous, defective, not of merchantable quality, and unfit for the ordinary purpose for which it is intended.

195. Defendants knew or had reason to know of these material facts, and wrongfully and fraudulently concealed these material facts from Plaintiff and the Breach of Implied Warranty Subclass. Plaintiffs and the Breach of Implied Warranty Subclass were induced to purchase and ingest ranitidine, including Zantac, under false or fraudulent pretenses.

196. Had Defendants disclosed all material information regarding ranitidine, including Zantac, described above, Plaintiff and the Breach of Implied Warranty Subclass would not have purchased and consumed Zantac.

197. Plaintiff and the Breach of Implied Warranty Subclass reasonably relied on Defendants' skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

198. Defendants knew or had reason to know that Plaintiff and the Breach of Implied Warranty Subclass would rely on Defendants' skill and judgment.

199. Defendants' breach of implied warranties proximately caused Plaintiff and the Breach of Implied Warranty Subclass members to suffer damages.

200. Plaintiffs and the Breach of Implied Warranty Subclass seek compensatory damages, attorneys' fees and costs, in addition any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

**COUNT IX: NEGLIGENCE AND GROSS NEGLIGENCE AGAINST THE  
GLAXOSMITHKLINE DEFENDANTS**

201. Plaintiff Lynn White incorporates by reference all preceding and subsequent paragraphs.

202. This claim is brought by Plaintiff on behalf of herself and the Nationwide Class - GlaxoSmithKline.

203. Defendants have a duty to exercise ordinary care in the design, manufacturing, marketing and sale of their pharmaceutical products, such as ranitidine, including Zantac.

204. Defendants also have a duty to exercise reasonable care when they undertake affirmative acts for the protection of others.

205. Defendants have a duty to refrain from selling unreasonably dangerous products, and to ensure that their products such as ranitidine, do not cause users to suffer from foreseeable risks of harm.

206. Defendants have a continuing duty to warn of adverse effects associated with their pharmaceutical products.

207. Defendants owed these duties to Plaintiffs and the Nationwide Class because it was foreseeable that Plaintiffs and the members of the Nationwide Class would rely on their skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

208. Defendants breached those duties for the reasons alleged herein.

209. Defendants breached their duties when they ignored or concealed scientific evidence regarding ranitidine's dangerous properties, failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

210. Defendants conduct directly and proximately injured Plaintiff and the Nationwide Class - GlaxoSmithKline because they have been exposed to NDMA, which is a known carcinogen and has been connected to various types of cancer.

211. Cancer has a latency period of many years, and all during this time, Plaintiff lives in constant fear that she will develop cancer because she was exposed to harmful levels of NDMA.

212. Early detection is oftentimes the best means to treat cancer. Therefore, in addition to compensatory damages for Defendants negligence and gross negligence, Plaintiff and the Nationwide Class also seek the implementation and funding of a medical monitoring program.

213. The medical monitoring is to provide necessary testing and screening for various types of cancer that have been linked to ranitidine and NDMA, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

214. The medical monitoring is also to provide for necessary medical and surgical procedures for diagnosis and treatment.

**COUNT X: NEGLIGENCE AND GROSS NEGLIGENCE AGAINST THE SANOFI  
DEFENDANTS**

215. Plaintiff Lynn White incorporates by reference all preceding and subsequent paragraphs.

216. This claim is brought by Plaintiff on behalf of herself and the Nationwide Class - Sanofi.

217. Defendants have a duty to exercise ordinary care in the design, manufacturing, marketing and sale of their pharmaceutical products, such as ranitidine, including Zantac.

218. Defendants also have a duty to exercise reasonable care when they undertake affirmative acts for the protection of others.

219. Defendants have a duty to refrain from selling unreasonably dangerous products, and to ensure that their products such as ranitidine, do not cause users to suffer from foreseeable risks of harm.

220. Defendants have a continuing duty to warn of adverse effects associated with their pharmaceutical products.

221. Defendants owed these duties to Plaintiffs and the Nationwide Class because it was foreseeable that Plaintiffs and the members of the Nationwide Class would rely on their skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

222. Defendants breached those duties for the reasons alleged herein.

223. Defendants breached their duties when they ignored or concealed scientific evidence regarding ranitidine's dangerous properties, failed to disclose information regarding the

relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

224. Defendants conduct directly and proximately injured Plaintiff and the Nationwide Class - Sanofi because they have been exposed to NDMA, which is a known carcinogen and has been connected to various types of cancer.

225. Cancer has a latency period of many years, and all during this time, Plaintiff lives in constant fear that she will develop cancer because she was exposed to harmful levels of NDMA.

226. Early detection is oftentimes the best means to treat cancer. Therefore, in addition to compensatory damages for Defendants negligence and gross negligence, Plaintiff and the Nationwide Class also seek the implementation and funding of a medical monitoring program.

227. The medical monitoring is to provide necessary testing and screening for various types of cancer that have been linked to ranitidine and NDMA, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

228. The medical monitoring is also to provide for necessary medical and surgical procedures for diagnosis and treatment.

**COUNT XI: NEGLIGENCE AND GROSS NEGLIGENCE AGAINST THE DR.  
REDDY'S DEFENDANTS**

229. Plaintiff Nataliya Birman incorporates by reference all preceding and subsequent paragraphs.

230. This claim is brought by Plaintiff on behalf of herself and the Nationwide Class – Dr. Reddy's.

231. Defendants have a duty to exercise ordinary care in the design, manufacturing, marketing and sale of their pharmaceutical products, such as ranitidine, including Zantac.

232. Defendants also have a duty to exercise reasonable care when they undertake affirmative acts for the protection of others.

233. Defendants have a duty to refrain from selling unreasonably dangerous products, and to ensure that their products such as ranitidine, do not cause users to suffer from foreseeable risks of harm.

234. Defendants have a continuing duty to warn of adverse effects associated with their pharmaceutical products.

235. Defendants owed these duties to Plaintiffs and the Nationwide Class because it was foreseeable that Plaintiffs and the members of the Nationwide Class would rely on their skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

236. Defendants breached those duties for the reasons alleged herein.

237. Defendants breached their duties when they ignored or concealed scientific evidence regarding ranitidine's dangerous properties, failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

238. Defendants conduct directly and proximately injured Plaintiff and the Nationwide Class – Dr. Reddy's because they have been exposed to NDMA, which is a known carcinogen and has been connected to various types of cancer.

239. Cancer has a latency period of many years, and all during this time, Plaintiff lives in constant fear that she will develop cancer because she was exposed to harmful levels of NDMA.



240. Early detection is oftentimes the best means to treat cancer. Therefore, in addition to compensatory damages for Defendants negligence and gross negligence, Plaintiff and the Nationwide Class also seek the implementation and funding of a medical monitoring program.

241. The medical monitoring is to provide necessary testing and screening for various types of cancer that have been linked to ranitidine and NDMA, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

242. The medical monitoring is also to provide for necessary medical and surgical procedures for diagnosis and treatment.

**COUNT XII: NEGLIGENCE AND GROSS NEGLIGENCE AGAINST THE  
GLENMARK DEFENDANTS**

243. Plaintiff Nataliya Birman incorporates by reference all preceding and subsequent paragraphs.

244. This claim is brought by Plaintiff on behalf of herself and the Nationwide Class - Glenmark.

245. Defendants have a duty to exercise ordinary care in the design, manufacturing, marketing and sale of their pharmaceutical products, such as ranitidine, including Zantac.

246. Defendants also have a duty to exercise reasonable care when they undertake affirmative acts for the protection of others.

247. Defendants have a duty to refrain from selling unreasonably dangerous products, and to ensure that their products such as ranitidine, do not cause users to suffer from foreseeable risks of harm.

248. Defendants have a continuing duty to warn of adverse effects associated with their pharmaceutical products.

249. Defendants owed these duties to Plaintiffs and the Nationwide Class because it was foreseeable that Plaintiffs and the members of the Nationwide Class would rely on their skill and judgment to provide a safe and suitable product, because Defendants are in the business of designing and manufacturing pharmaceuticals.

250. Defendants breached those duties for the reasons alleged herein.

251. Defendants breached their duties when they ignored or concealed scientific evidence regarding ranitidine's dangerous properties, failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

252. Defendants conduct directly and proximately injured Plaintiff and the Nationwide Class - Glenmark because they have been exposed to NDMA, which is a known carcinogen and has been connected to various types of cancer.

253. Cancer has a latency period of many years, and all during this time, Plaintiff lives in constant fear that she will develop cancer because she was exposed to harmful levels of NDMA.

254. Early detection is oftentimes the best means to treat cancer. Therefore, in addition to compensatory damages for Defendants negligence and gross negligence, Plaintiff and the Nationwide Class also seek the implementation and funding of a medical monitoring program.

255. The medical monitoring is to provide necessary testing and screening for various types of cancer that have been linked to ranitidine and NDMA, including but not limited to colorectal, kidney, stomach, bladder, nasopharynx, and esophageal cancer.

256. The medical monitoring is also to provide for necessary medical and surgical procedures for diagnosis and treatment.

**COUNT XIII: FRAUDULENT CONCEALMENT AGAINST THE GLAXOSMITHLINE DEFENDANTS**

257. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

258. This claim is brought by Plaintiff Lynn White on behalf of herself and the Nationwide Class - GlaxoSmithKline.

259. At all relevant times, Defendants held out ranitidine, including Zantac, to be free from defects and to be safe for consumers. At the same time, Defendants willfully ignored or concealed scientific evidence regarding ranitidine's dangerous properties, consciously failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

260. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Defendants intentionally concealed from Plaintiff and the Nationwide Class material information that Zantac was defective and unsafe.

261. Defendants also affirmatively misrepresented to Plaintiff and the Nationwide Class in advertising and other forms of communication, including standard and uniform material provided with the drug's packing, that ranitidine, including Zantac, had no significant defects and was safe to use and consume.

262. All of the above facts were known or knowable to Defendants, but were not known or knowable to Plaintiff or the Nationwide Class.

263. Plaintiff and the Nationwide Class had no knowledge of or access to scientific literature or technical information regarding ranitidine's dangerous properties and/or the relationship between ranitidine and NDMA and cancer.

264. Plaintiff and the Nationwide Class relied on Defendants' concealment, misrepresentations, and deception when purchasing ranitidine, including Zantac.

265. Had Defendants disclosed all material information regarding ranitidine, described above, Plaintiff and the Nationwide Class would not have purchased and consumed it.

266. The foregoing acts and omissions proximately caused Plaintiff and Nationwide Class members to suffer damages.

267. Plaintiff and the Class seek compensatory damages, attorneys' fees and costs, in addition to any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

268. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

**COUNT XIV: FRAUDULENT CONCEALMENT AGAINST THE SANOFI  
DEFENDANTS**

269. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

270. This claim is brought by Plaintiff Lynn White on behalf of herself and the Nationwide Class - Sanofi.

271. At all relevant times, Defendants held out ranitidine, including Zantac, to be free from defects and to be safe for consumers. At the same time, Defendants willfully ignored or concealed scientific evidence regarding ranitidine's dangerous properties, consciously failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

272. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Defendants intentionally concealed from Plaintiff and the Nationwide Class material information that Zantac was defective and unsafe.

273. Defendants also affirmatively misrepresented to Plaintiff and the Nationwide Class in advertising and other forms of communication, including standard and uniform material provided with the drug's packing, that ranitidine, including Zantac, had no significant defects and was safe to use and consume.

274. All of the above facts were known or knowable to Defendants, but were not known or knowable to Plaintiff or the Nationwide Class.

275. Plaintiff and the Nationwide Class had no knowledge of or access to scientific literature or technical information regarding ranitidine's dangerous properties and/or the relationship between ranitidine and NDMA and cancer.

276. Plaintiff and the Nationwide Class relied on Defendants' concealment, misrepresentations, and deception when purchasing ranitidine, including Zantac.

277. Had Defendants disclosed all material information regarding ranitidine, described above, Plaintiff and the Nationwide Class would not have purchased and consumed it.

278. The foregoing acts and omissions proximately caused Plaintiff and Nationwide Class members to suffer damages.

279. Plaintiff and the Class seek compensatory damages, attorneys' fees and costs, in addition to any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

280. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

**COUNT XV: FRAUDULENT CONCEALMENT AGAINST THE DR. REDDY'S DEFENDANTS**

281. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

282. This claim is brought by Plaintiff Nataliya Birman on behalf of herself and the Nationwide Class – Dr. Reddy's.

283. At all relevant times, Defendants held out ranitidine, including Zantac, to be free from defects and to be safe for consumers. At the same time, Defendants willfully ignored or concealed scientific evidence regarding ranitidine's dangerous properties, consciously failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

284. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Defendants intentionally concealed from Plaintiff and the Nationwide Class material information that Zantac was defective and unsafe.

285. Defendants also affirmatively misrepresented to Plaintiff and the Nationwide Class in advertising and other forms of communication, including standard and uniform material provided with the drug's packing, that ranitidine, including Zantac, had no significant defects and was safe to use and consume.

286. All of the above facts were known or knowable to Defendants, but were not known or knowable to Plaintiff or the Nationwide Class.

287. Plaintiff and the Nationwide Class had no knowledge of or access to scientific literature or technical information regarding ranitidine's dangerous properties and/or the relationship between ranitidine and NDMA and cancer.

288. Plaintiff and the Nationwide Class relied on Defendants' concealment, misrepresentations, and deception when purchasing ranitidine, including Zantac.

289. Had Defendants disclosed all material information regarding ranitidine, described above, Plaintiff and the Nationwide Class would not have purchased and consumed it.

290. The foregoing acts and omissions proximately caused Plaintiff and Nationwide Class members to suffer damages.

291. Plaintiff and the Class seek compensatory damages, attorneys' fees and costs, in addition to any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.

292. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

**COUNT XVI: FRAUDULENT CONCEALMENT AGAINST THE GLENMARK DEFENDANTS**

293. Plaintiff incorporates by reference all preceding and subsequent paragraphs.

294. This claim is brought by Plaintiff Nataliya Birman on behalf of herself and the Nationwide Class – Glenmark.

295. At all relevant times, Defendants held out ranitidine, including Zantac, to be free from defects and to be safe for consumers. At the same time, Defendants willfully ignored or concealed scientific evidence regarding ranitidine's dangerous properties, consciously failed to disclose information regarding the relationship between ranitidine and NDMA and cancer, and

made knowing and intentional statements and misrepresentations about the safety of ranitidine, all of which were material, false, and/or misleading.

296. Rather than complying with its reporting, disclosure, warning, and labeling obligations, Defendants intentionally concealed from Plaintiff and the Nationwide Class material information that Zantac was defective and unsafe.

297. Defendants also affirmatively misrepresented to Plaintiff and the Nationwide Class in advertising and other forms of communication, including standard and uniform material provided with the drug's packing, that ranitidine, including Zantac, had no significant defects and was safe to use and consume.

298. All of the above facts were known or knowable to Defendants, but were not known or knowable to Plaintiff or the Nationwide Class.

299. Plaintiff and the Nationwide Class had no knowledge of or access to scientific literature or technical information regarding ranitidine's dangerous properties and/or the relationship between ranitidine and NDMA and cancer.

300. Plaintiff and the Nationwide Class relied on Defendants' concealment, misrepresentations, and deception when purchasing ranitidine, including Zantac.

301. Had Defendants disclosed all material information regarding ranitidine, described above, Plaintiff and the Nationwide Class would not have purchased and consumed it.

302. The foregoing acts and omissions proximately caused Plaintiff and Nationwide Class members to suffer damages.

303. Plaintiff and the Class seek compensatory damages, attorneys' fees and costs, in addition to any and other legal and equitable relief to which they are entitled, including but not limited to the implementation and funding of a medical monitoring program.



304. Plaintiff and the Nationwide Class also seek punitive damages because Defendants' conduct was malicious, intentional, and knowing, and exhibited an extreme disregard for the health and welfare of Plaintiff and the Nationwide Class.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs, individually and on behalf all others similarly situated, request that this Court:

- A. Enter an order certifying this action as a class action under Federal Rule of Civil Procedure 23(a), (b)(1), (b)(2), (b)(3), and/or (c)(4), as appropriate; appointing Plaintiffs as representative of the Classes; and appointing the undersigned counsel as Class counsel;
- B. Award Plaintiffs and the Classes damages, including but not limited to the amounts that they spent on ranitidine, including Zantac, and any other compensatory damages to which they are entitled;
- C. Award treble damages or punitive damages as allowed by law;
- D. Award equitable relief, including but not limited to the implementation and funding of a medical monitoring program;
- E. Award reasonable attorneys' fees and costs, as provided for by law; and
- F. Grant such other and further relief that the Court may deem just and proper.

### **JURY DEMAND**

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff requests a trial by jury of all issues triable as of right.

Dated: November 25, 2019

Lynn White and Nataliya Birman,  
individually and on behalf of all  
others similarly situated,

By: /s/ Elizabeth A. Fegan

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